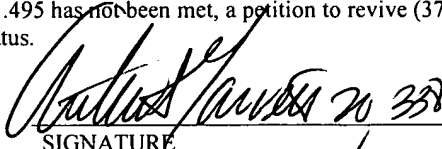


FORM PTO-1390 REV. 2/01T		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	COMMER NO. 22,852 ATTORNEY'S DOCKET NUMBER 09617.0001
<b>TRANSMITTAL LETTER TO THE UNITED STATES          DESIGNATED/ELECTED OFFICE (DO/EO/US)          CONCERNING A FILING UNDER 35 U.S.C. 371</b>			U.S. APPLICATION NO. (If known, see 37CFR1.5) 10/510,627 <span style="float: right;">#4</span>
INTERNATIONAL APPLICATION NO. <b>PCT/JP03/04531</b>	INTERNATIONAL FILING DATE April 9, 2003	PRIORITY DATE CLAIMED April 9, 2002	
TITLE OF INVENTION METHOD OF JUDGING LEUKEMIA, PRE-LEUKEMIA OR ALEUKEMIC MALIGNANT BLOOD DISEASE AND DIAGNOSTIC THEREFOR			
APPLICANT(S) FOR DO/EO/US Kiyoshi ANDO, Tomomitsu HOTTA, Chie ITO, Hidenao SATO, Akiko FURUYA, Kenya SHITARA, Seiji SUGIMOTO, Hiroaki KOHNO			
Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C 371. 2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)). a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed with the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154 (d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)). a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).			
<b>Items 11 to 20 below concern document(s) or information included:</b>			
11. <input type="checkbox"/> Information Disclosure Statement under 37 CFR 1.97 and 1.98 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A Substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154 (d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4). 20. <input checked="" type="checkbox"/> Other items or information: a. <input type="checkbox"/> Copy of cover page of International Publication No. WO 03/085399 A1 b. <input checked="" type="checkbox"/> Copy of Notification of Missing Requirements. c. <input checked="" type="checkbox"/> Sequence Listing in Written form consisting of 8 sheets d. <input checked="" type="checkbox"/> Statement Under 37 CFR § 1.821			

U.S. APPLICATION NO. (If known, see 37CFR 1.5) <b>10/510,627</b>		INTERNATIONAL APPLICATION NO. <b>PCT/JP03/04531</b>		ATTORNEY'S DOCKET NUMBER <b>09617.0001</b>	
21. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
<b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b>  Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... <b>\$1110.00</b>  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$950.00</b>  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... <b>\$790.00</b>  International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$750.00</b>  International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33 (1)-(4) ..... <b>\$100.00</b>  <div style="text-align: right;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b> \$</div>					
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). <span style="float: right;"><input type="checkbox"/> 20    <input checked="" type="checkbox"/> 30</span>				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	45	- 20 =	25	x \$18.00	\$
Independent Claims	11	-3 =	8	x \$88.00	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+\$300.00	\$
<b>TOTAL OF THE ABOVE CALCULATIONS =</b>				\$130.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
<b>SUBTOTAL =</b>				\$130.00	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest priority date (37 CFR 1.492(f)). <span style="float: right;"><input type="checkbox"/> 20    <input type="checkbox"/> 30</span>				\$	
<b>TOTAL NATIONAL FEE =</b>				\$130.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property. <span style="float: right;">+</span>				\$	
<b>TOTAL FEES ENCLOSED =</b>				\$130.00	
<b>130.00 OP</b>				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>130.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-0916</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status. <b>SEND ALL CORRESPONDENCE TO:</b> Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001-4413					
DATED: June 20, 2005				<div style="text-align: center;">             SIGNATURE            Ernest F. Chapman            NAME/REGISTRATION NO. 25,961         </div>	

06/23/2005 LLANDGRA 00000021 10510627  
01 FC:1617



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/510,627	Kiyoshi Ando	09617.0001

INTERNATIONAL APPLICATION NO.

PCT/JP03/04531

LA. FILING DATE

PRIORITY DATE

04/09/2003

04/09/2002

22852  
 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
 LLP  
 901 NEW YORK AVENUE, NW  
 WASHINGTON, DC 20001-4413

CONFIRMATION NO. 4183

371 FORMALITIES LETTER



\*OC000000015761186\*

Date Mailed: 04/18/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 10/08/2004
- English Translation of the IA filed on 10/08/2004
- Copy of the International Search Report filed on 10/08/2004
- Copy of IPE Report filed on 10/08/2004
- Information Disclosure Statements filed on 10/08/2004
- Biochemical Sequence Diskette filed on 10/08/2004
- Biochemical Sequence Listing filed on 10/08/2004
- U.S. Basic National Fees filed on 10/08/2004
- Priority Documents filed on 10/08/2004

**RECEIVED**

APR 20 2005

FINNEGAN, HENDERSON, FARABOW,  
 GARRETT AND DUNNER, LLP

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patent Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patent Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

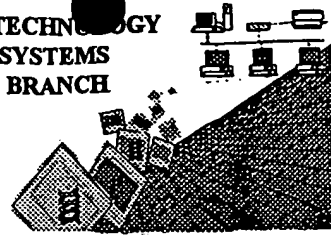
*A copy of this notice **MUST** be returned with the response.*

WINSTON M ALVARADO

Telephone: (703) 308-9140 EXT 206

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/510,627	PCT/JP03/04531	09617.0001



## RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/510,627

Source: P4/10

Date Processed by STIC: 10/16/04

**THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.**

**PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:**

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

**FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221**

**TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:**

**<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>**

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)

2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 06/05/04):

U.S. Patent and Trademark Office, 220 20<sup>th</sup> Street S., Customer Window, Mail Stop Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, VA 22202

Revised 05/17/04

*Please mail this report with the 905.*

Winston Alvarado  
National Stage Processing  
Patent Specialist  
(703) 305-8421



PCT

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/510,627

DATE: 10/16/2004

TIME: 08:51:44

Input Set : N:\FATIMA\10510627.txt

Output Set: N:\CRF4\10162004\J510627.raw

3 <110> APPLICANT: TOKAI UNIVERSITY  
 4 KYOWA HAKKO KOGYO CO., LTD.  
 5 KYOWA MEDEX CO., LTD.  
 7 <120> TITLE OF INVENTION: A diagnostic method and a diagnostic agent for  
 8 leukemia, preleukemia and leukemic malignant hemopathy  
 10 <130> FILE REFERENCE: 11470WO1  
 C--> 12 <140> CURRENT APPLICATION NUMBER: US/10/510,627  
 C--> 13 <141> CURRENT FILING DATE: 2004-10-08  
 15 <150> PRIOR APPLICATION NUMBER: JP P2002-106786  
 16 <151> PRIOR FILING DATE: 2002-04-09  
 18 <160> NUMBER OF SEQ ID NOS: 11  
 20 <170> SOFTWARE: PatentIn Ver. 2.1

## ERRORED SEQUENCES

270 <210> SEQ ID NO: 11  
 271 <211> LENGTH: 18  
 272 <212> TYPE: DNA  
 273 <213> ORGANISM: Artificial Sequence  
 W--> 275 <220> FEATURE:  
 W--> 275 <223> OTHER INFORMATION:  
 W--> 275 <400> 11  
 276 ttttgggggc tttggtgg  
 E--> 288 8/8

delete

*pp 1-3*  
 Does Not Comply  
 Corrected Diskette Needed

*see p. 2 for error explanation*

18

RAW SEQUENCE LISTING ERROR SUMMARY  
PATENT APPLICATION: US/10/510,627

DATE: 10/16/2004  
TIME: 08:51:45

Input Set : N:\FATIMA\10510627.txt  
Output Set: N:\CRF4\10162004\J510627.raw

*error explanation*

Use of <220> Feature (NEW RULES):

Sequence(s) are missing the <220> Feature and associated headings.

Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial Sequence" or "Unknown". Please explain source of genetic material in <220> to <223> section (See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)

Seq#: 8, 9, 10, 11.

*each of these sequences has the above error*

*see p. 3 for more errors*

10/50,627 3

..Ala Leu Gly Leu Pro Ala Gly Arg Gly Asp Glu Asn Pro Ala Gly Thr

35

40

45

1/8

T do not show page  
numbers in the computer  
readable file of the  
Sequence Listing

please  
remove  
all page  
numbers  
in submitted  
Sequence Listing  
file

(per 1.824 of Sequence Rules,



VERIFICATION SUMMARY

PATENT APPLICATION: US/10/510,627

DATE: 10/16/2004

TIME: 08:51:45

Input Set : N:\FATIMA\10510627.txt

Output Set: N:\CRF4\10162004\J510627.raw

L:12 M:270 C: Current Application Number differs, Replaced Application Number  
 L:13 M:271 C: Current Filing Date differs, Replaced Current Filing Date  
 L:228 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:0  
 L:247 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:8, <213>  
 ORGANISM:Artificial Sequence  
 L:247 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:8, <213>  
 ORGANISM:Artificial Sequence  
 L:247 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:8,Line#:247  
 L:252 M:259 W: Allowed number of lines exceeded, <210> SEQ ID NO  
 L:257 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:9, <213>  
 ORGANISM:Artificial Sequence  
 L:257 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:9, <213>  
 ORGANISM:Artificial Sequence  
 L:257 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:9,Line#:257  
 L:266 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:10, <213>  
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 ORGANISM:Artificial Sequence  
 L:266 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:10,Line#:266  
 L:275 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:11, <213>  
 ORGANISM:Artificial Sequence  
 L:275 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:11, <213>  
 ORGANISM:Artificial Sequence  
 L:275 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:11,Line#:275  
 L:288 M:254 E: No. of Bases conflict, LENGTH:Input:8 Counted:19 SEQ:11  
 L:288 M:320 E: (1) Wrong Nucleic Acid Designator, NUMBER OF INVALID KEYS:2  
 L:288 M:252 E: No. of Seq. differs, <211> LENGTH:Input:18 Found:19 SEQ:11